REMARKS

The Advisory Action of June 4, 2007 states that the Amendments and Remarks dated May 4, 2007 in response to the Final Action of January 17, 2007 overcame the previous rejections under 35 USC 112, first paragraph, but that they raised a new issue under 35 USC 112, second paragraph. Thus, with one minor exception, the claim amendments and remarks made herewith are identical to those made in the Response to Final Action mailed on May 4, 2007. The only exception is that claims 38 and 42 have been further amended to address the Examiner's comments regarding a possible issue under 112, second paragraph. Specifically, pursuant to the Examiner's suggestion set forth in the Advisory Action, the phrase "wherein said probe hybridizes to a β3Gal-T5 and not to β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members" has been amended to recite "wherein said probe hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members."

In this response it is also noted that a new Terminal Disclaimer has been submitted in order to reflect that the owner Henrik Clausen is an owner of 100% interest in the application (and therefore the terminal disclaimer now properly disclaims 100% interest in the recited patent).

Claims 38 and 42 have been amended by way of the instant amendment. Claims 38 and 41-43 are pending.

Claims 38 and 42 have been amended to recite that the "probe hybridizes with the entire length of a second nucleic acid." Support for this amendment can be found throughout the specification, for example, on page 9, lines 5-7 and page 26, line 30 – page 27, line 2. Claims 38 and 42 have also been amended to recite "hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members." Support for this amendment can be found throughout the specification, for example, on page 9, lines 13-27. Accordingly, no new matter has been added by way of the claim amendments.

Claim rejections under 35 U.S.C. §§ 101 and 112, first paragraph, utility

Claims 38 and 41-43 have been rejected under 35 U.S.C. §§ 101 and 112, first paragraph because the specification allegedly fails to provide a specific and substantial asserted utility or a well established utility. According to the Examiner, "[o]ther than ... SEQ ID NO: 8, the specification provides little functional characterization of [the claimed] polynucleotide." Further, the Examiner contends that identifying the polynucleotides as "probes" in the claims "is not a utility specific to the claimed polynucleotide sequence since the claim does not make it clear as to what or which polynucleotide can be probed using the claimed polynucleotide." The Examiner continues "Applicants erroneously conclude that since the specification explains or discloses the polynucleotide encoding β3Gal-T5, claims are automatically limited to probes or target polynucleotides having said property."

Without conceding the Examiner's position, claims 38 and 41-43 have been amended to recite that the "probe hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members." Accordingly, these claims recite a specific and substantial utility, the identification of β3Gal-T5 genes. Accordingly, Applicants submit that the claimed nucleic acid probes of this invention have a specific and substantial utility in accordance with 35 U.S.C. § 101. Applicants therefore respectfully request that the rejections under 35 U.S.C. §§ 101 and 112, first paragraph be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph, enablement

Claims 38 and 41-43 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner acknowledges that the specification enables an isolated polynucleotide of less than 10,000 nucleotides wherein the polynucleotide hybridizes to the specified regions of SEQ ID NO: 8 under the recited hybridization conditions and wherein the "polynucleotide is a full length polypeptide having [β3Gal-T5] encoding activity." According to the Examiner, the specification does not enable "any such polynucleotide or a complement thereof which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO: 8 or

nucleotides 428-1011 of SEQ ID NO: 8 under stringent conditions of claim 1 and exhibits no encoding activity." The Examiner contends that the claims are not enabled because: "Simply put, above claims encompass variants of polynucleotide sequence of SEQ ID NO: 8 which have no function of encoding a functional polypeptide and applicants have not taught those skilled in the art as to where exactly on the polynucleotide sequence of SEQ ID NO: 8 specific nucleotides can be modified ... and how to select those modified sequence that show any utility" (Office Action, page 5).

Without conceding the Examiner's position, the claims have been amended to recite that the probe hybridizes with the entire length of a second nucleic acid (comprising nucleotides 1-115 of SEQ ID NO: 8 in the case of claim 38 (and the complement thereof for claim 41) and comprising nucleotides 428-1011 of SEQ ID NO: 8 in the case of claim 42 (and the complement thereof for claim 43)). Thus, the probes of claims 38 and 41 must be at least 115 nucleotides long and the probes of claims 42 and 43 must be at least 583 (1011 minus 428) nucleotides long. The claims have also been amended to recite that the probe hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members.

The claims are not directed to nucleic acids encoding polypeptides that necessarily possess β3Gal-transferase activity. The claims are directed to probes having a minimal length (115 nucleotides for claims 38 and 41 and 583 nucleotides for claims 42 and 43)and maximal length (less than 10,000 nucleotides) and that hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members. A "probe" is "a nucleic acid that forms a hybrid structure with a sequence in a target region due to complementarily [sic] of at least one sequence in the probe with a sequence in the target region" (specification, page 10, lines 1-3). Thus, these claims require the skilled artisan to identify: (1) an isolated nucleic acid or complement thereof of less than 10,000 contiguous nucleotides, which (2) hybridizes with the entire length of a second nucleic acid comprising a specified sequence and length under (3) certain hybridization conditions and (4) hybridizes to polynucleotides encoding β3Gal-T5 and not other family members. Each of these steps can be routinely performed by one of

ordinary skill in the art without undue experimentation. None of these steps require that the probe encode anything. Accordingly, the claims are enabled and this rejection should be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 38 and 41-43 have been rejected under 35 U.S.C. § 112, first paragraph because the Examiner contends that the specification "does not contain any disclosure of the function of all DNA sequences that simply hybridize to nucleotides 1-115 or nucleotides 428-1011 of SEQ ID NO: 8 under the [recited] stringency conditions." The Examiner further states "Examiner's main contention is that claims are simply drawn to probes that one skilled in the art would be subject to undue experimentation first to make it and next to use it. If according to the applicant claims are simply drawn to "probes" that [do] not require either the target nucleotides or probes themselves to encode any protein having an established activity, then the question arises as to how those skilled in the art would use those probes."[1]

Without conceding the Examiner's position claims 38 and 42 have been amended to recite that the probe hybridizes to a polynucleotide encoding a β3Gal-T5 and not to polynucleotides encoding β3Gal-T1, β3Gal-T2, β3Gal-T3, or β3Gal-T4 family members. Additionally, a minimal length has been required of the claimed probes (115 nucleotides for the probes of claims 38 and 41 and 583 nucleotides for the probes of claims 42 and 43) and this length must hybridize over the entire length of a specific sequence (nucleotides 1-115 of SEQ ID NO: 8 for claims 38 and 41 and nucleotides 428-1011 of SEQ ID NO: 8 for claims 42 and 43). Accordingly, significant information about the structure and function of the claimed probes has been explicitly set forth in the claims and one of ordinary skill in the art would recognize how to make and use these probes.

Accordingly, the function of the claimed nucleic acid probes has been sufficiently set forth in the claims; Applicants respectfully request withdrawal of this rejection.

[1] Applicants would like to point out that this last statement is a mischaracterization of the Applicants arguments in the previously filed response. Specifically, it was argued that "The claims are not directed to nucleic acids encoding polypeptides that necessarily possess β3Gal-transferase activity." It was not argued, as the Examiner contends here, that

Claim rejections under 35 U.S.C. § 102(b)

Claims 38 and 41 have been rejected under 35 U.S.C. § 102(b) as anticipated by Szulzewsky et al. (GenBank Accession No. AJ003597, December 4, 1997). According to the Examiner, Szulzewsky discloses a polynucleotide that has a greater than 90% sequence identity to nucleotides 93-115 of SEQ ID NO: 8. The Examiner contends that this nucleotide hybridizes to at least 20 contiguous nucleotides of 93-115 of SEQ ID NO: 8 under the recited stringency conditions.

Without conceding the Examiner's position, claim 38 has been amended to recite that the "probe hybridizes with the entire length of a second nucleic acid comprising nucleotides 1-115 of SEQ ID NO: 8." Szulzewsky discloses a 338 nucleotide sequence in which nucleotides 314-335 have an about 91% identity match to nucleotides 93-115 of the 933 nucleotide sequence represented by SEQ ID NO: 8. Accordingly, Szulzewsky does not disclose or suggest a probe that hybridizes with the entire length of a nucleic acid comprising nucleotides 1-115 of SEQ ID NO: 8. Thus, this rejection has been obviated; Applicants respectfully request its withdrawal.

Rejections under the Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected claims 38-41 under the judicially created doctrine of obviousness type double patenting over claims 1-10 of U.S. Patent No. 6,800,468. In the Advisory Action, the Examiner indicated that the Terminal Disclaimer filed on May 4, 2007 was not approved because it only disclaimed a 50% interest by one of the inventors.

In order to correct the terminal disclaimer, a new Terminal Disclaimer is submitted herewith in which it is properly stated that the owner, Henrik Clausen, is an owner of 100% interest in the instant application (and therefore the terminal disclaimer now properly disclaims 100% interest in the recited patent). Therefore, withdrawal of this rejection is respectfully requested.

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the target nucleotides do not encode any protein that has an established activity. In fact, the target nucleotide must either encode a functional protein or be a fragment of a gene that encodes a functional protein.

The fee under 37 CFR § 1.20(d) was paid with the May 4, 2007 terminal disclaimer. Thus it is believed that no further terminal disclaimer fee is due. However, should the U.S. Patent and Trademark Office determine that any other fee(s) is due or that any refund is owed for this application, the Commissioner is hereby authorized and requested to charge the required fee(s) and/or credit the refund(s) owed to our Deposit Account No. 04-0100.

Conclusion

Applicants believe that this application is in condition for allowance. Favorable early action is respectfully requested. No new matter has been added.

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Respectfully submitted,

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